

WHAT IS CLAIMED IS:

1. A pharmaceutical composition having enhanced solubility comprising a drug and polyethylene glycol, wherein the ratio of polyethylene glycol to drug by weight is from about 0.2:1 to about 10:1, and the polyethylene glycol has a melting point of at least 37°C.
2. A pharmaceutical composition having enhanced solubility comprising a drug and polyethylene glycol, wherein the ratio of polyethylene glycol to drug by weight is from about 0.5:1 to about 5:1, and the polyethylene glycol has a melting point of at least 37°C.
3. A pharmaceutical composition having enhanced solubility comprising a drug and polyethylene glycol, wherein the ratio of polyethylene glycol to drug by weight is from about 0.7:1 to about 2:1, and the polyethylene glycol has a melting point of at least 37°C.
4. The composition according to Claim 3, wherein the weight ratio of polyethylene glycol to drug is about 1:1.
5. The composition according to Claim 1, wherein the polyethylene glycol has a melting point of at least 50 °C.
6. The composition according to Claim 1, wherein the drug is a hydrophobic drug.
7. The composition according to Claim 6, wherein the hydrophobic drug is selected from the group consisting of raloxifene, paroxetine, glimepiride, anagrelide, modafinil, cabergoline, replaginide, glipizide, benzodiazepines, clofibrate, chlorpheniramine, dinitrate, digoxin, digitoxin, ergotamin tartate, estradiol, fenofibrate, griseofulvin, hydrochlorothiazide, hydrocortisone, isosorbide, medrogeston, oxyphenbutazone, prednisolone, prednisone, polythiazide, progensterone, spironolactone, tolbutamide, 10,11-dihydro-5H-dibenzo[a,d]cyclo-heptene-5-carboxamide; 5H-dibenzo[a,d]cycloheptene-5-carboxamide, fish oil and combinations thereof.
8. The composition according to Claim 7, wherein the hydrophobic drug is selected from the group consisting of raloxifene, paroxetine, glimepiride, anagrelide and modafinil.
9. The composition according to Claim 1, wherein the polyethylene glycol has the formula $\text{HOCH}_2(\text{CH}_2\text{OCH}_2)_n\text{CH}_2\text{OH}$, wherein n is from 20-204.

10. The composition according to Claim 9, wherein the polyethylene glycol has an average molecular weight from about 950 to about 20,000.
11. The composition according to Claim 10, wherein the polyethylene glycol has an average molecular weight from about 2700 to about 9000.
12. The composition according to Claim 9; wherein the polyethylene glycol is selected from the group consisting of PEG 1000, PEG 1500, PEG 1540, PEG 2000, PEG 3000, PEG 4000, PEG 4500, PEG 6000, PEG 8000 and PEG 20000.
13. The composition according to Claim 1, which is essentially free of a surfactant.
14. The composition according to Claim 1, which additionally comprises a surfactant.
15. The composition according to Claim 14, wherein the surfactant is selected from the group consisting of reaction products of a natural or hydrogenated castor oil and ethylene oxide, polyoxyethylene-sorbitan-fatty acid esters, polyoxyethylene fatty acid esters, polyoxyethylene-polyoxypropylene co-polymers and block co-polymers, dioctylsulfosuccinate or di-[2-ethylhexyl]-succinate, phospholipids, propylene glycol mono- and di-fatty acid esters, polyoxyethylene alkyl ethers, tocopherol esters, docusate salts and combinations thereof.
16. The composition according to Claim 15, wherein the surfactant is a polyoxyethylene-sorbitan-fatty acid ester.
17. The composition according to Claim 16, wherein the polyoxyethylene-sorbitan-fatty acid ester is selected from the group consisting of polyoxyethylene(20)sorbitanmonolaurate, polyoxyethylene(4)sorbitanmonolaurate, polyoxyethylene(20)sorbitanmonopalmitate, polyoxyethylene(20)sorbitanmonostearate, polyoxyethylene(20)sorbitantristearate, polyoxyethylene(20)sorbitanmonooleate, polyoxyethylene(5)sorbitanmonooleate, and polyoxyethylene(20)sorbitantrioleate.
18. The composition according to Claim 17, wherein the polyoxyethylene-sorbitan-fatty acid ester is polyoxyethylene(20)sorbitanmonooleate.
19. The composition according to Claim 14, wherein the surfactant is present in an amount of from about 0.01 wt % to about 20 wt %, based on the total weight of the composition.

20. The composition according to Claim 19, wherein the surfactant is present in an amount of from about 1 wt % to about 5 wt %, based on the total weight of the composition.

21. The composition according to Claim 1, which additionally comprises at least one excipient.

22. The composition according to Claim 21, wherein the excipient is selected from the group consisting of enteric coating agents, diluents, binders, anti caking agents, amino acids, fibers, solubilizers, disintegrants, fillers, lubricants, emulsifiers, flavorants, solvents, buffers, stabilizers, colorants, dyes, anti-oxidants, anti-adherents, preservatives, electrolytes, glidants, carrier materials and combinations thereof.

23. The composition according to Claim 1, which is in the form selected from the group consisting of a tablet, granules, bar, block, disc, capsule, caplet and powder.

24. A method of preparing a pharmaceutical composition having enhanced solubility comprising a drug and polyethylene glycol, wherein the ratio of polyethylene glycol to drug by weight is from about 0.2:1 to about 10:1, and the polyethylene glycol has a melting point of at least 37°C, said method comprising:

- (a) combining polyethylene glycol with a drug and optionally one or more excipients to form a premix;
- (b) adding a solvent and optionally a surfactant to the premix formed in Step (a) to form a wet granulation; and
- (c) drying the wet granulation to form a pharmaceutical composition.

25. A method of preparing a pharmaceutical composition having enhanced solubility comprising a drug and polyethylene glycol, wherein the ratio of polyethylene glycol to drug by weight is from about 0.2:1 to about 10:1, and the polyethylene glycol has a melting point of at least 37°C, said method comprising:

- (a') combining a drug and optionally one or more excipients to form a premix;
- (b') adding a mixture comprising a solvent and polyethylene glycol to the premix formed in Step (a') to form a wet granulation; and
- (c') drying the wet granulation to form a pharmaceutical composition.

26. A method of preparing a pharmaceutical composition having enhanced solubility comprising a drug and polyethylene glycol, wherein the ratio of polyethylene glycol to drug by weight is from about 0.2:1 to about 10:1, and the polyethylene glycol has a melting point of at least 37°C, said method comprising:

(a'') combining a drug with melted polyethylene glycol and optionally a surfactant to form a slurry; and

(b'') cooling the slurry formed in Step (a'') to form a solid;

(c'') milling the solid formed in Step (b'') to form granules, and

(d'') mixing at least one excipient with the granules to form a pharmaceutical composition.